UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

FWK HOLDINGS, LLC, on behalf of itself and all others similarly situated, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS CORPORATION, ENDO PHARMACEUTICALS, INC., ENDO INTERNATIONAL PLC, and PAR PHARMACEUTICAL, INC., Defendants.	Civil Action No.: 18-5886 CLASS ACTION COMPLAINT JURY TRIAL DEMANDED

Plaintiff FWK Holdings, LLC ("FWK" or "Plaintiff"), on behalf of itself and all others similarly situated, for its complaint against Novartis Pharmaceuticals Corporation, Novartis AG, and Novartis Corporation (collectively, "Novartis"), and Endo Pharmaceuticals, Inc., Endo International plc and Par Pharmaceutical, Inc. (collectively, "Par") ("Defendants" refers to Novartis and Par, collectively), based upon personal knowledge as to facts pertaining to itself, and upon information and belief as to all other matters, alleges as follows:

I. Introduction and Relevant Background

1. This is a civil antitrust action seeking treble damages arising out of Defendants' unlawful scheme to allocate and monopolize the market for Exforge® ("Exforge"), a U.S. Food and Drug Administration ("FDA") approved prescription drug product for the treatment of hypertension comprising the active ingredients amlodipine and valsartan. Plaintiff seeks overcharge damages arising out of Novartis's unlawful agreement with Par not to compete in the market for Exforge and corresponding AB-rated generic drug products.

2. Prior to market entry of generic equivalents of Exforge, Novartis's U.S. sales of branded Exforge exceeded $400 million annually.

3. The FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations," colloquially known as the "Orange Book," had three Novartis patents listed for Exforge: (1) U.S. Patent No. 5,399,578 (the "'578 Patent" which expired on September 21, 2012); (2) U.S. Patent No. 6,294,197 (the "'197 Patent," which expired on June 18, 2017); and (3) U.S. Patent No. 6,395,728 (the "'728 Patent," which has not yet expired).

4. In or around October and November 2007, generic manufacturers Par and Synthon Pharmaceuticals Inc. ("Synthon")—recognizing the market potential of a generic Exforge

product—filed Abbreviated New Drug Applications ("ANDA") with the FDA seeking approval to market generic amlodipine and valsartan tablets, with Exforge as the Reference Listed Drug.

5. Par filed an ANDA for the 10/160, 5/160 and 10/320 milligram strengths of amlodipine and valsartan, respectively, while Synthon filed for the 5/320 milligram strength. On information and belief, in their ANDAs, Par and Synthon addressed the three Novartis patents by indicating that: (1) they would not seek final FDA approval until the September 21, 2012 expiration of exclusivities associated with the '578 Patent, however, (2) they would seek final FDA approval to market, and intended to launch, their ANDA products prior to the expiration of the follow-on patents—the '197 and '728 Patents—which they claimed were invalid and/or would not be infringed by their proposed generic equivalents.

6. On November 30, 2011, Par entered into an asset purchase agreement with Synthon under which Par would acquire Synthon's ANDA. One month later, the agreement closed.

7. Upon information and belief, in or around 2011—upon learning of Par's ANDA containing potential challenges to the '197 and '728 Patents—Par and Novartis reached an agreement (the "Agreement") under which (1) Par agreed not to compete in the market for fixed combinations of amlodipine and valsartan until September 30, 2014, allocating the entire Exforge market to Novartis for years beyond the 2012 expiration of the unchallenged '578 Patent, and (2) Novartis agreed not to compete, in the form of an authorized generic version ("AG") version of Exforge, in the generic Exforge market from September 30, 2014 until March 30, 2015, allocating the generic market of Exforge to Par for six months.

8. Upon information and belief, the Agreement centered on Novartis's agreement to refrain from launching an AG version of Exforge for the first six months after Par's delayed launch, thereby depriving the market of an additional competitor and lower prices.

9. On March 19, 2010, the FDA granted tentative approval to Par's ANDA, determining that Par's ANDA had satisfied all bioequivalence, chemistry, manufacturing, controls ("CMC"), and labeling requirements.

10. On March 28, 2013, the FDA granted final approval to Par's ANDA.

11. Because of Defendants' unlawful Agreement and conduct, Par did not release its approved generic version of Exforge until September 30, 2014, and for a period of six months thereafter, the only generic available for Plaintiff and other direct purchasers was Par's product.

12. But for Defendants' Agreement and scheme, one or more generic versions of Exforge would have entered the market as early as September 21, 2012—when the '578 Patent's exclusivities expired—but no later than March 29, 2013 (when Par's 180-day exclusivity expired), and the vast majority of sales would have gone to less expensive generics. As alleged below, Defendants' scheme injured Plaintiff and the Class of direct purchasers it seeks to represent (as defined below), causing them to pay overcharges for brand and generic Exforge.

13. Defendants' unlawful Agreement: (1) delayed and/or precluded the entry of less-expensive generic versions of Exforge; (2) precluded the introduction of an Exforge AG from Novartis that otherwise would have appeared on the market at an earlier time; (3) fixed, raised, maintained, or stabilized prices of fixed combinations of amlodipine and valsartan; and (4) permitted Novartis to maintain a monopoly for fixed combinations of amlodipine and valsartan.

14. By and through the Agreement, Novartis and Par afforded themselves a guarantee of higher revenues both during the period in which Par agreed to delay generic entry and during Par's 180-day period of generic market exclusivity, all of which resulted in anticompetitive overcharges to direct purchasers like Plaintiff. The "basic reason" for the Agreement was

Defendants' "desire to maintain and to share patent-generated monopoly profits" and therefore the Agreement is "likely" unlawful. *FTC v. Actavis, Inc.*, 570 U.S. 136, 158 (2013).

15. As alleged in more detail below, Defendants violated sections 1 and 2 of the Sherman Act through their contract and conspiracy to restrain trade by foreclosing competition from lower-priced AB-rated generic versions of Exforge. Through their Agreement and conduct, Defendants improperly maintained and extended Novartis's market and monopoly power by foreclosing or delaying competition from lower-priced generic versions of fixed combinations of amlodipine and valsartan.

16. The agreement for Par to delay market entry in exchange for, *inter alia*, Novartis's reciprocal agreement during Par's 180-day exclusivity period to forego the launch of an AG, is a naked market allocation scheme that is *per se* illegal.

17. Novartis and Par—ostensible competitors—conspired to allocate the market for Exforge and its generic equivalents in a manner that gave each company more exclusivity than each was entitled to in order to maximize profits at the expense of direct purchasers of Exforge.

18. Defendants' anticompetitive Agreement caused harm to the direct purchasers of Exforge by causing them to pay artificially-inflated prices for Exforge and generic versions of Exforge. Plaintiff, and all others similarly situated, were injured and sustained damages in the form of overcharges for branded and generic forms of Exforge as a direct result of Novartis's and Par's unlawful Agreement. Absent Defendants' unlawful Agreement, Plaintiff and the members of the Class would have benefited from competition for generic versions of Exforge earlier than they did and would have been able to purchase fixed combinations of amlodipine and valsartan at significantly lower prices substantially earlier. This civil antitrust case seeks overcharges (trebled) paid by Plaintiff and a class of all other persons or entities in the U.S. who purchased Exforge

directly from Novartis and/or generic Exforge tablets directly from Par at any time during the Class Period from September 21, 2012 (or earlier, if pediatric exclusivity did not apply), until the effects of Defendants' conduct cease.

II. Parties

19. Plaintiff FWK Holdings, LLC ("FWK") is an Illinois limited-liability corporation with its principal place of business in Glen Ellyn, Illinois. FWK is the assignee of antitrust claims possessed by Frank W. Kerr Company ("Kerr") and brings this action as successor-in-interest to Kerr's claims arising from its purchase of Exforge and generic Exforge directly from one or more of the Defendants during the Class Period. As a result of Defendants' antitrust conspiracy, FWK, through its assignor Kerr, paid supra-competitive prices for its purchases of branded and generic Exforge and was injured by the illegal conduct alleged herein.

20. Defendant Novartis Pharmaceuticals Corporation is a Delaware corporation with its principal place of business is at One Health Plaza, East Hanover, New Jersey 07936, and locations in New York, New Jersey and California. It is a subsidiary of Defendant Novartis Corporation, and an indirect subsidiary of Defendant Novartis AG, and is the New Drug Application ("NDA") holder (and was the NDA applicant) for, and a distributor of, Exforge. As the pharmaceuticals unit of defendants Novartis Corporation and Novartis AG, Novartis Pharmaceuticals Corporation develops, manufactures, sells, and markets Novartis Corporation's and Novartis AG's drugs in the U.S.

21. Defendant Novartis AG is a Swiss corporation, having an office and a place of business in Basel.

22. Defendant Novartis Corporation is a New York corporation with its principal place of business at One Health Plaza, East Hanover, New Jersey 07936. Novartis Corporation, the

parent corporation of Defendant Novartis Pharmaceuticals Corporation, is effectively the U.S. headquarters of its Swiss parent, Defendant Novartis AG. Novartis Corporation handles the administration, sales, and marketing of a wide variety of prescription drugs, vaccines, consumer medicines, and veterinary products.

23. Defendant Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business at 300 Tice Blvd, Woodcliff Lake, New Jersey 07677. Par Pharmaceutical, Inc. principally develops, manufactures, and markets generic versions of brand name drugs.

24. Defendant Endo Pharmaceuticals, Inc. is a Delaware corporation, with its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania 19355.

25. Defendant Endo International plc is an Irish private limited company with its principal place of business in Dublin, and a U.S. headquarters at 1400 Atwater Drive, Malvern, Pennsylvania, 19355, where its wholly-owned subsidiary, defendant Endo Pharmaceuticals, Inc., is based. Endo Pharmaceuticals, Inc. and Endo International plc are referred to collectively here as "Endo." On September 28, 2015, Defendant Endo completed an acquisition of Defendant Par Pharmaceutical, Inc. Endo assumed all of Par Pharmaceutical, Inc.'s liabilities upon acquiring it.

26. All of Defendants' actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, or with the actual, apparent, or ostensible authority of Defendants.

III. Jurisdiction and Venue

27. This action arises under sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover treble damages, costs of suit, and reasonable attorneys' fees for the injuries sustained by FWK and members of the Class resulting from Defendants' contract and conspiracy to restrain trade in the U.S. market for Exforge and its generic equivalents. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), 1407, and 15 U.S.C. § 15.

28. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because during the class period, Defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of the alleged activity that affected interstate trade and commerce as discussed below has been carried out in this District.

29. Defendants' conduct, as described in this Complaint, was within the flow of, was intended to, and did have a substantial effect on, the interstate commerce of the U.S., including in this District.

30. During the Class Period (defined below), Novartis and Par manufactured, sold, and shipped Exforge and generic Exforge in a continuous and uninterrupted flow of interstate commerce. The contract and conspiracy in which Defendants participated had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

31. During the Class Period each Defendant, or one or more of its affiliates, used the instrumentalities of interstate commerce to join or effectuate their contract and conspiracy.

32. This Court has personal jurisdiction over each Defendant, because each Defendant—throughout the U.S. and including in this District—has transacted business, maintained substantial contacts, and/or committed overt acts in furtherance of its illegal conduct and conspiracy. The conduct and conspiracy have been directed at, and have had the intended

effect of, causing injury to persons residing in, located in, or doing business throughout the U.S., including in this District.

IV. Regulatory Background

A. The Regulatory Structure for Approval and Substitution of Generic Drugs

33. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing an NDA. 21 U.S.C. §§ 301-92. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents. 21 U.S.C. § 355(a), (b).

34. When the FDA approves a brand manufacturer's NDA, the manufacturer may list in the Orange Book any patents that the manufacturer believes could reasonably be asserted against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents. The manufacturer may list in the Orange Book within thirty days of issuance any patents issued after the FDA approved the NDA. 21 U.S.C. §§ 355(b)(1), (c)(2).

35. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability as it does not have the resources or authority to verify the manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial task.

1. The Hatch-Waxman Amendments

36. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an ANDA. An ANDA relies on the scientific findings of safety and effectiveness

included in the brand manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug. This establishes that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to and are of the same dosage strength and form as their brand counterpart an "AB" rating.

37. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same extent and for the same amount of time as the brand counterpart. 21 U.S.C. § 355(j)(8)(B).

38. Congress enacted the Hatch-Waxman Amendments to expedite the entry of less-expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

39. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historic high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for brand and generic drugs totaled $21.6 billion; by 2013, total prescription drug

revenue had climbed to more than $329.2 billion, with generic drugs accounting for 86% of prescriptions.[1] Generics are dispensed 95% of the time when a generic form is available.[2]

2. ANDA Paragraph IV Certification

40. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic drug will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

i. that no patent for the brand drug has been filed with the FDA ("Paragraph I certification");

ii. that the patent for the brand drug has expired ("Paragraph II certification");

iii. that the patent for the brand drug will expire on a particular date and the manufacturer does not seek to market its generic product before that date ("Paragraph III certification"); or

iv. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product ("Paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

41. If a generic manufacturer files a Paragraph IV certification, it must notify the brand manufacturer, and the brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the Paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months (the "30-month stay"), or (b) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. §

[1] *See* IMS INSTITUTE FOR HEALTHCARE INFORMATICS, MEDICINE USE AND SHIFTING COSTS OF HEALTHCARE, at 30, 51 (Apr. 1, 2014), *available at* https://democrats-oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/IMS-Medicine%20use%20and%20shifting%20cost%20of%20healthcare.pdf (last accessed June 19, 2018).
[2] *Id.* at 51.

355(j)(5)(B)(iii). Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot grant final approval authorizing the generic manufacturer to market its product. The FDA may grant a tentative approval to an ANDA when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay or the existence of an unexpired patent for which the generic filer has submitted a Paragraph III certification (that the generic does not intend to market the ANDA product prior to the expiration of the patent).

42. If a brand manufacturer does not bring suit within 45 days of receiving notification of the Paragraph IV certification, it will not be entitled to a 30-month stay, and the FDA will not be prevented from granting final approval to the ANDA assuming other regulatory requirements (such as bioequivalence) are satisfied.

3. First-Filer's 180-Day Exclusivity Period

43. Generics may be classified as (i) first-filer generics, (ii) later generic filers, and (iii) the brand's own authorized generic.

44. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first generic manufacturer who files a substantially complete ANDA with a Paragraph IV certification (the "first-filer") a 180-day period to market the generic version of the drug, during which the FDA may not grant final approval to any other manufacturer's ANDA for a generic version of the same brand drug. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D). That is, when a first-filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the brand product are either invalid or not infringed by the generic's product, the FDA cannot approve a later generic company's ANDA until that first-filing generic has been on the market for 180-days, or

until the first-filer exclusivity has been forfeited. The 180-day window is referred to as the first-filer's six month or 180-day "exclusivity."

45. The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly worth several hundred million dollars" to the first filer. *Actavis*, 570 U.S. at 144 (citation omitted).

46. A first-filer that informs the FDA that it intends to wait until all Orange Book-listed patents expire before marketing its product does not get a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents, or to invent around such patents by creating non-infringing generics.

47. Although later generic ANDA filers must wait 180 days after the first-filer's market entry to get final FDA approval, a brand drug manufacturer can launch an AG version of its own brand drug, under its own NDA, at any time—including during the 180-day exclusivity period—and brand companies frequently do so in response to generic entry to recoup some of the sales they would otherwise lose. An AG is simply the brand product sold under generic trade dress at a cheaper price than the brand. Because the AG is already approved under the brand manufacturer's NDA, it can be marketed at any time, including during the first-filer's 180-day exclusivity period.

B. The Competitive Effects of AB-Rated Generic Competition

48. Generic versions of brand drugs contain the same active ingredient and the FDA determines them to be just as safe and effective as their brand counterparts. The only material difference between generic drugs and their corresponding brand versions is their price. Because generic versions of a corresponding brand drug product are commodities that cannot be differentiated, the primary basis for generic competition is price. Typically, generics are at least 10% less expensive (and on average 30% less expensive) than their brand counterparts when there

is a single generic competitor. This discount typically increases to 50% – 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic drug usually results in significant cost savings for all drug purchasers.

49. Since the passage of the Hatch-Waxman Amendments, every state has adopted laws that either require or permit pharmacies to automatically substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician has specifically ordered otherwise). Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic that the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic equivalent enters the market, the generic quickly captures sales of the corresponding brand drug, often capturing 80% or more of the brand's sales within the first six months. The Federal Trade Commission ("FTC") found that on average, within a year of generic entry, generics had captured 90% of corresponding brand drug sales and (with multiple generics on the market) prices had dropped 85%.[3] As a result, competition from generic drugs is viewed by brand drug companies, such as Novartis, as a severe threat to their profit margins.

50. Generic competition enables all purchasers to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand drug at a reduced price.

51. Until a generic version of the brand drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. Brand

[3] *See* FTC, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS (Jan. 2010) ("FTC Pay-for-Delay Study), *available at* http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf (last accessed June 19, 2018).

manufacturers, such as Novartis, are well aware of generics' rapid erosion of their brand sales. Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes (as here) resorting to illegal means.

1. The First AB-Rated Generic is Priced Below the Brand

52. Experience and economic research demonstrates that the first generic manufacturer to launch prices its product below the price of its brand counterpart.[4] Every state either requires or permits that a prescription written for the brand drug be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the brand form of the drug. At the same time, there is a reduction in average price paid for a prescription for the drug at issue (brand and AB-rated generic combined).

53. During the 180-day exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market (as noted above, the brand's AG can be, and often is, on the market during the 180-day exclusivity period). As recognized by the Supreme Court, it is often the case that most of a first-filer's profits are earned during the 180-day exclusivity period. *See Actavis*, 570 U.S. at 143-44.

54. If there is no AG on the market during the 180-day exclusivity period, the first-filer prices its product below the brand product, but not as low as if it were facing competition from other generics, including an AG. Where in these circumstances that the first-filer's product competes only with the brand product, and because the brand company rarely drops the brand

[4] FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT, at ii-iii, 34 (Aug. 2011) ("FTC 2011 AG Study"), *available at* https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf (last accessed June 19, 2018); FTC Pay-for-Delay Study, at 1.

product price to match the first-filer, the first-filer does not face the kind of price competition it will when additional generic products—including an AG—are available. Thus, a first-filer earns much greater sales and profits without an AG being marketed alongside it during the 180-day exclusivity period.

2. Later Generics Drive Prices Down Further

55. Once multiple generic competitors enter the market, the competitive process accelerates and multiple generic sellers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.[5]

56. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some typical estimates are that a single generic launch results in a near term retail price reduction of around 30%, but that with two generic entrants near term retail price reduction is about 50% or more.

57. Soon after generic competition begins, the vast majority of the sales formerly enjoyed by the brand shift to generic sellers. A 2011 FTC Study found that generics captured 80% or more of sales in the first six months.[6] In the end, total payments to the brand manufacturer of the drug decline to a small fraction of the amounts paid prior to generic entry. This is so because, although generic drugs are chemically identical to their brand counterparts, they are typically sold

[5] *See*, *e.g.*, Patricia Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, J.L. & ECON. (Oct. 2000); Tracy Regan, *Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market*, INT'L J.L. INDUS. ORG. (Aug. 2007); R. Frank, *The Ongoing Regulation of Generic Drugs*, NEW ENG. J. MED., v. 357, pp. 1993-96 & n.20 (Nov. 2007).

[6] FTC 2011 AG Study, at 66-67.

at substantial discounts from the brand price. Generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics.

3. AGs Compete on Price, Like Other Generics

58. Nothing prevents a brand manufacturer from selling an AG at any time. An AG is chemically identical to the brand drug, but is sold as a generic product typically through either the brand manufacturer's subsidiary (if it has one) or through a third-party distributor. An AG is essentially the brand drug but in a different package. One study noted, "pharmaceutical developers facing competition from generics have large incentives to compete with their own or licensed 'authorized generics.'"[7] Brand manufacturers sometimes begin selling AGs before the first-filer generic launches in order to secure multi-year purchase contracts with direct purchasers and load the generic pipeline at the expense of the first-filer generic.

59. Competition from an AG substantially reduces drug prices and the revenue of the first-filer generic (especially during the 180-day exclusivity period when no other generic can be on the market).

60. A study analyzing three examples of AGs found that "[f]or all three products, authorized generics competed aggressively against independent generics on price, and both the authorized and independent generics captured substantial market share from the brand."[8] In a report by the FTC issued at the request of Congress in 2011, the FTC found that AGs capture a significant portion of sales, reducing the first-filer generic's revenues by approximately 50% on average.[9] The first-filer generic makes significantly less money when it faces competition from

[7] K. A. Hassett & R. J. Shapiro, *The Impact of Authorized Generic Pharmaceuticals on the Introduction of Other Generic Pharmaceuticals*, SONECON, p. 3 (May 2007).
[8] E. R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, HEALTH AFFAIRS, v. 26, p. 796 & n.3 (May/June 2007).
[9] FTC 2011 AG Study, at 139.

an AG because (a) the AG takes a large share of unit sales away from the first filer and (b) the presence of the AG causes prices—particularly generic prices—to decrease. Thus, if a brand manufacturer agrees to refrain from launching its AG, it can double the first-filer's revenue during the 180-day exclusivity period.

61. While a brand manufacturer's agreement not to launch an AG has tremendous financial value to a first-filer generic manufacturer, such an agreement, when used to induce the first-filer to delay its own launch, injures drug purchasers in two ways: (1) purchasers are forced to pay the high brand prices for longer than they otherwise would have; and (2) purchasers pay more for the generic in the absence of the AG. In fact, the 2011 FTC AG Study shows prices with AG entry are lower during the 180-day exclusivity period.[10] Drug purchasers (including the proposed Class of direct purchasers) benefit from the lower prices caused by AG entry and are injured by the higher prices resulting from no AG competition.

62. Freedom from an AG is exceedingly valuable to the first-filer because it hands over all generic sales at higher, supra-competitive prices. Consequently, some brand companies (such as Novartis) wield the right to launch an AG as a powerful tool to induce the first-filer generic (such as Par) to delay its entry. The promise of payment to the first-filer generic in the form of an agreement not to launch an AG is economically equivalent to the promise of a cash payment by the brand manufacturer to the generic manufacturer because refraining from launching an AG under the agreement effectively and predictably doubles the revenues and profits of that generic company from its generic drug, and the brand manufacturer forgoes the sales and revenues it otherwise would have made with its AG. It's as if the brand launched the AG, then handed over its revenues to the first-filer.

[10] FTC 2011 AG Study, at 113-14.

63. For a first-filer (like Par) seeking to sell a generic version of a brand product that sold hundreds of millions of dollars annually (like Exforge), the difference between selling its generic alone, without having to compete against an AG, versus selling in competition with an AG, can amount to hundreds of millions of dollars. These economic realities are well known in the pharmaceutical industry. "No AG" agreements thus allow competitors to benefit from an agreement not to compete and deny purchasers the consumer surplus that should flow to them from increased competition.

C. Brand and Generic Companies Have Strong Financial Incentives to Enter Into Anticompetitive Agreements

64. An anticompetitive agreement entered into between the brand and first-filer generic subjects later ANDA filers to the delayed entry date agreed to between the brand manufacturer and its conspiring first-filer generic.

65. Later ANDA filers have more modest financial prospects because they have no expectation of any form of market exclusivity. By the time they enter the market there is at least the brand and one other generic on the market (if not also a second, in the form of an authorized generic) and thus, the drug has already been commoditized.

66. In the absence of an anticompetitive agreement between the brand company and the first-filer, the later ANDA filers have pro-competitive incentives. They are motivated to expend resources to challenge the brand company's patent (knowing that the first-filer generic is also fighting a patent infringement suit) and to enter the market as early as possible.

67. When an anticompetitive agreement with the first-filer is already in place, however, litigation becomes less attractive to later filers. The later generic manufacturers know that the first-filer is not leading the charge against the brand's patent (and has sometimes stipulated to the validity or enforceability of the patents as part of an anticompetitive agreement). The later generics

have to bear the brunt of the litigation costs themselves, and, upon prevailing in the patent litigation, expect to face competition from at least the first filer generic, and typically an AG as well.

68. Thus, some later generics decide to simply give in to, or even join, the conspiracy between the brand company and the first-filer generic and decide to drop their challenges to the brand's patents.

69. Exclusion payment agreements are fundamentally anticompetitive and are contrary to the goals of the Hatch-Waxman statutory scheme. In particular, they extend the brand manufacturer's monopoly profits by blocking access to more affordable generic drugs, forcing purchasers to buy the expensive brands instead.

70. Here, Novartis's and Par's illegal Agreement resulted in unlawful monopolization in the market for Exforge and its AB-rated generic equivalents. Novartis delayed generic entry by buying off Par, the first-filer generic. The *quid pro quo* for Par's agreement to delay competing in the market for Exforge was compensation Novartis provided to Par, including cash and/or non-cash value. On information and belief, Novartis made a large payment to Par through an agreement to refrain from marketing an AG of Exforge and/or some other commercial arrangement whose fair market value constituted a net payment to Par.

V. Statement of Facts

A. Defendants' Products and the Nature of Sales of AB (Generic Equivalent) Products

71. One in four adults—roughly a billion people worldwide—have high blood pressure. The disorder is the leading cause of risk-attributable death, accounting for more than seven million deaths per year, and every five seconds a person dies from a hypertension-related disease.

72. On June 20, 2007, the FDA approved Novartis's NDA for Exforge tablets. Shortly thereafter, Novartis introduced Exforge tablets to market.

73. Exforge was the first high blood pressure medication to combine the most commonly prescribed branded high blood pressure medicines in their respective classes: the calcium channel blocker ("CCB") amlodipine besylate (marketed under the brand name Norvasc) and the angiotensin-II receptor blocker ("ARB") valsartan (marketed under the brand name Diovan).

74. Novartis, owning Diovan, sought to combine the active ingredients in Diovan and Norvasc (a Pfizer product) as soon as Pfizer's patents expired in September 2007. On March 22, 2007, the Federal Circuit invalidated Pfizer's Norvasc patents, paving the way for FDA approval.

75. Novartis claimed that Exforge—the brand name for the combination of valsartan and amlodipine—offered patients the convenience of a reduced pill load for their hypertension medication, thus increasing patient adherence to their hypertension-reduction regimen.

B. Novartis's Exforge Patents

76. Novartis listed three patents in the Orange Book for Exforge (NDA No. 21-990): (1) the '578 Patent; (2) the '197 Patent; and (3) the '728 Patent. The '578 Patent, which disclosed and claimed the chemical compound valsartan, was due to expire on March 21, 2012. A regulatory exclusivity known as pediatric exclusivity[11] attached to the '578 Patent, extended the patent's expiry by six months, to September 21, 2012.

77. The '197 and '728 Patents did not, in and of themselves, afford Novartis the ability to exclude generic competition for Exforge. Novartis therefore had no legitimate basis for

[11] As a result of conducting tests in pediatric age groups, the FDA granted Novartis a six-month regulatory exclusivity.

excluding generic competition after September 21, 2012. Had the '197 or '728 Patents been litigated in court, they would have been adjudged invalid, unenforceable, and/or not infringed.

78. On or about October 1, 2007, Par filed an ANDA, No. 90-011. March 28, 2013 FDA Approval Letter at 1. Par's ANDA included Paragraph IV certifications for the '197 and '728 Patents. *Id.* at 2.

79. According to the FDA, the Paragraph IV certifications stated that "each of these [two] patents is invalid, unenforceable, or will not be infringed by [Par's] manufacture, use, or sale of Amlodipine and Valsartan Tablets, 5 mg/160 mg, 10 mg/160 mg, and 10 mg/320 mg" described in ANDA No. 90-011. *Id.* Par notified Novartis of its Paragraph IV certifications and the bases for them, but Novartis never filed a patent infringement suit. *Id.* On information and belief, the patent defenses set forth in Par's Paragraph IV certification notice letter were meritorious and would have succeeded had they been litigated.

a. The '728 Patent

80. Par's filing of ANDA No. 90-011, as well as its manufacture or sale of a generic version of Exforge, would not have infringed the '728 Patent. The claims of the '728 Patent are properly construed to be limited to the use of a combination of valsartan and amlodipine for the treatment of hypertension in a limited subset of patients suffering from diabetes. It could not have afforded Novartis any right to exclude generic competition beyond that narrow use.

81. In addition, the claims of the '728 Patent are invalid in view of the prior art. U.S. Patent No. 5,492,904 (the "'904 Prior Art Patent") issued on February 20, 1996—more than three years before the earliest possible effective filing date of the '728 Patent. The patent application that issued as the '904 Prior Art Patent was filed on July 28, 1994, whereas the prior art '578 Patent (disclosing valsartan) issued on March 21, 1995. The '904 Prior Art Patent was thus filed before

valsartan was publicly disclosed and is prior to both the '578 and '728. Upon the issuance of the '578 Patent (disclosing valsartan), it would have been obvious to use valsartan in the combination treatment taught by the '904 Prior Art Patent.

b. The '197 Patent

82. No valid claim of the '197 Patent was infringed by Par's filing of ANDA No. 90-011 or the manufacture or sale of Par's generic version of Exforge. The '197 Patent issued on September 25, 2001 from an application filed on June 18, 1997. It includes fifty-three (53) claims, of which only four are independent. "It is axiomatic that dependent claims cannot be found infringed unless the claims from which they depend have been found to be infringed." *Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989).

83. Each of the independent claims in the '197 Patent requires a compressed solid dosage form (or a process for forming or method of using such a compressed solid dosage form) comprising either (1) greater than 35% by weight valsartan; and/or (2) the active ingredient hydrochlorothiazide ("HCTZ") in combination with valsartan. Neither Exforge nor any generic version of Exforge contains or could contain the active ingredient HCTZ. Accordingly, the claims of the '197 Patent could cover a generic version of Exforge only if valsartan were present at greater than 35% by weight of the dosage form. On information and belief, at all relevant times Par's generic version of Exforge contained less than 35% by weight valsartan and thus could not literally infringe any of the claims of the '197 Patent. And, as a matter of law, the claims of the '197 Patent cannot cover generic versions of Exforge that contain 35% or less by weight valsartan under the doctrine of equivalents.

84. In addition, the relevant claims of the '197 Patent are invalid in view of the prior art. The earliest effective filing date for the '197 Patent is June 18, 1997, and therefore, the '578

Patent that issued on March 21, 1995 (disclosing valsartan) is prior art to the '197 Patent. The '578 Patent anticipates claims of the '197 Patent, thereby rendering those claims invalid.

85. That Novartis never sued Par for patent infringement on either of these patents, despite Par filing an ANDA containing a Paragraph IV Certification for them, demonstrates Novartis's belief that its patents did not afford it any right to exclude Par from marketing generic Exforge.

C. Par and Synthon File ANDAs for Generic Versions of Exforge, But Novartis Does Not Sue

86. Par and Synthon—recognizing the market potential for Exforge—in or about the fall of 2007, filed the first ANDAs with the FDA containing Paragraph IV certifications to certain Exforge patents.

87. Par filed ANDA 90-011 on October 1, 2007 for the 10/160, 5/160, and 10/320 milligram strengths of Exforge. On information and belief, Par was the first applicant to file a substantially complete application containing a Paragraph IV certification for those three strengths, making it eligible for 180 days of regulatory exclusivity.

88. Synthon filed ANDA 90-144 on November 26, 2007 for the 5/320 milligram strength of Exforge. On information and belief, Synthon was the first applicant to file a substantially complete application containing a Paragraph IV certification for the 5/320 milligram strength, making it eligible for 180 days of regulatory exclusivity for that strength.

89. On information and belief, Par and Synthon addressed the Orange Book-listed Novartis patents for Exforge in their ANDA filings as follows: (1) they submitted Paragraph III certifications to the '578 Patent; and (2) they submitted Paragraph IV certifications to the '197 and '728 Patents.

90. On or shortly after October 1, 2007 and November 26, 2007, respectively, Par and Synthon disclosed their intention to market their AB-rated generic products as early as September 21, 2012.

91. Because Par and Synthon were the first companies to file substantially complete ANDAs with Paragraph IV certifications, they stood to receive a significant and potentially highly profitable benefit under 21 U.S.C. 355(j)(5)(B)(iv): 180 days of marketing exclusivity during which the FDA would not give final approval to any other ANDA filer's generic equivalent of Exforge.

92. On information and belief, after receiving confirmation of receipt from the FDA for their ANDAs, Par and Synthon sent notice to Novartis of their respective ANDAs containing Paragraph IV certifications in letters that included "a detailed factual and legal statement as to why" the '197 and '728 Patents were "invalid, unenforceable, and/or not infringed" by Par's or Synthon's ANDA Products (the "Paragraph IV Notices"). The Paragraph IV Notices included an offer of confidential access to Par's and Synthon's ANDAs as required under Hatch-Waxman. The Notices give rise to a cause of action under the Hatch-Waxman Act for infringement.

93. Novartis did not file a lawsuit against Par or Synthon. Accordingly, no 30-month stay went into effect.

94. On March 19, 2010, the FDA granted tentative approval to Par's ANDA for the generic version of Exforge, indicating its determination that, aside from existing patent or regulatory exclusivities, Par's generic Exforge was otherwise approvable and satisfied all bioequivalence, CMC, and labeling requirements.

95. As of March 19, 2010, and because Novartis had not sued Par, the only thing preventing Par from obtaining final FDA approval and launching its generic Exforge was the last

two-and-a-half years of protection afforded by the '578 Patent covering the active ingredient valsartan.

96. On information and belief, instead of suing, Novartis reached an agreement with Par to abandon its efforts to launch its generic version of Exforge at the earliest possible date after the expiration of the '578 Patent and instead agreed upon a delayed launch date of September 30, 2014—roughly two years after expiry of the '578 Patent. In exchange, Novartis agreed not to launch an Exforge AG for the first six months after Par's entry.

97. On information and belief, Novartis had weak patent claims that it was motivated to settle with a reverse payment in the form of a No-AG, rather than risking an adverse ruling on its patents. Evidence of the weakness of the '197 and '728 Patents includes:

a. Par's and Synthon's ability to develop and file ANDAs with Paragraph IV certifications within a few months of FDA approval of Exforge;

b. Novartis's decision not to sue for patent infringement and enforce its intellectual property in court; and

c. The facts set forth above and in Par's and Synthon's Paragraph IV certification notice letters.

98. But for the Agreement, Par would have been prepared, willing, and able to launch generic Exforge as early as September 21, 2012, but no later than March 29, 2013, and would have communicated as much to the FDA and requested final approval for its ANDAs well in advance of September 21, 2012.

99. By 2009, Exforge was already generating hundreds of millions of dollars per year in revenues for Novartis. Losing a substantial portion of that revenue stream upon expiry of the '578 Patent—as Novartis would have if the '197 and '728 Patents were held by a court to be

invalid, unenforceable, or not infringed, or if Par launched upon final FDA approval after expiry of the '578 Patent—would have drastically affected Novartis's profit margins. Novartis had enormous incentives to avoid patent infringement litigation and avoid competition from Par by entering into the Agreement.

100. While the existence of the Agreement was first disclosed in early 2012, the salient, and illegal, provision – that Novartis would not market an AG to compete with Par's delayed launch of its generic – did not become apparent until years after the Agreement was struck sometime in 2011. For example, a January 2012 analyst day presentation by Par lists a "Synthon/Exforge" "Business Development" arrangement in 2011. Par's 10-K for the fiscal year ending December 31, 2011 states "[o]n November 30, 2011, we entered into an asset purchase agreement with Synthon Pharmaceuticals, Inc., and on December 30, 2011, we closed on our acquisition, of Synthon's ANDA for amlodipine besylate and valsartan (5 mg/320 mg and 10 mg/320 mg) fixed dose combination tablets, a generic version of Exforge®, for $9,600 thousand. Under the terms of a separate license agreement with Novartis Pharmaceuticals Corporation, we have a certain launch date in October 2014." Nowhere in these disclosures did Par describe the Agreement's provisions regarding Novartis's agreement to not sell an AG in competition with Par's generic Exforge product.

101. Similarly, Novartis's 2011 20-F filed on January 25, 2012 stated, "In the US, under a license agreement with a generics manufacturer, the product [Exforge] is expected to face generic competition beginning in October 2014." However, nothing about Novartis's agreement to not sell an Exforge AG to compete with Par was disclosed. Indeed, until Novartis failed to launch an AG upon market entry by Par in September of 2014, it was not clear that Novartis intended to

forgo such a launch, as important details of the license agreement between Novartis and Par were deliberately concealed.

102. The six months of delay from Par's launch of its generic to Novartis's launch of an AG constituted consideration to Par.

103. On information and belief, in exchange for Par's agreement to forgo selling its generic products in competition with Novartis's branded Exforge product until almost two years after the expiration of the '578 Patent, Novartis agreed to share with Par the monopoly profits from sales of branded Exforge via a covenant not to compete with Par's generic through Novartis's own sale of an authorized generic. Instead of competing—which would have resulted in lower prices of both generic and branded Exforge—Novartis and Par agreed to keep prices of both products at supra-competitive levels.

104. The Agreement benefitted Par by guaranteeing that it would be the sole generic on the market during the 180-day exclusivity period, more than doubling Par's anticipated sales revenues in the exclusivity period because: (1) Par would capture all or substantially all of the sales that would have gone to the AG, and (2) Par would be able to charge significantly higher prices for its generic product without AG price competition. Par also benefited by delaying its launch of generic Exforge from September 21, 2012 to September 30, 2014 because Novartis could continue raising prices during that time, making the market more lucrative to divide once Par did launch.

105. A brand company's launch of its own competing AG is extremely costly to any first-filing generic (such as Par) because the AG splits generic sales and forces prices down. The AG also cuts into the first-filer's long term "first mover advantage." Novartis itself stated in public

SEC filings that "[t]he company that launches an [AG] typically launches its product at the same time as the generic exclusivity holder."

106. Novartis's covenant not to launch an AG during Par's exclusivity period was extremely valuable to Par and exceeded what Par could have otherwise achieved financially had it successfully litigated the '197 and '728 Patents. As Novartis stated in its regulatory filings, "[AG]s also reduce the value of the exclusivity for the company that invested in creating the first generic medicine to compete with the originator product. Furthermore, certain research-based companies continually seek new ways to protect their products and to decrease the impact of generic competition, thus potentially limiting the profit that the generic companies can earn on the competing generic product."

107. Absent the unlawful Agreement, it would make economic sense for Novartis to launch an AG during Par's 180-day marketing exclusivity so that Novartis could retain some of the sales that Par's less expensive generic otherwise would capture.

108. As alleged above, an AG typically captures approximately 50% of the generic sales during the first 180 days of generic marketing. As early as May 2006, financial analysts were projecting annual peak sales for Exforge of $500 million. Similarly, during Novartis AG's third quarter, 2007 earnings call, Thomas Ebeling, the CEO of its pharma division, expressed optimism that Exforge would become a "blockbuster drug" in the U.S., which is an industry shorthand for drugs that reach $1 billion in sales. By 2014, Novartis's annual Exforge sales were over $400 million. Using the most conservative of these numbers, Defendants could assume that 6 months of sales would likely generate revenue of at least $200 million.

109. As is common in the pharmaceutical industry, the first generic is expected to take 80% (or more) of the brand sales. Thus, approximately $160 million worth of brand sales would

be converted to the generic. As is also common, with only one generic on the market, the generic is typically priced at 90% of the brand, which would result in generic sales of approximately $144 million. Thus, the sales revenue during the 180-day exclusivity period that would reasonably have been anticipated by Par under the no-AG deal would be approximately $144 million.

110. Par's expectations would have differed dramatically if Novartis had not promised to refrain from introducing an AG. While the generics would still take 80% of brand sales, or $160 million, the generic sales value would drop to $83.2 million. And, it would reasonably be expected that those sales would be split evenly between Par and Novartis's AG. Without the no-AG Agreement, Par's share of the revenue from sales of generic Exforge during the first 6 months would be expected to be approximately $41.6 million.

111. As a result, the expected value to Par of facing no AG versus facing typical AG competition would have been approximately $102.4 million. Novartis's agreement to not launch an AG for 6 months was thus a payment to Par of $102.4 million or more. The value of this payment to Par was no different than if Novartis handed $102.4 million to Par in cash.[12]

112. Novartis—which owns the generic company, Sandoz, Inc., which often launches AGs—has a history of launching AG versions of its own blockbuster branded products in the face of actual or impending competition from ANDA-based generics. The FTC has found that, in the time period from 2001 to 2008—which encompasses the Agreement, here—only three companies launched more authorized generics than Novartis. S*ee* FTC, Authorized Generic Drugs: Short-

[12] The FTC has concluded that, when free from competition from an authorized generic, "the first-filer's revenue will approximately double" during the first six months of generic competition, compared to what the first filer would make if it faced authorized generic competition. FTC, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG- TERM IMPACT vi (2011), *available at* http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf. The Supreme Court has recognized this as well. *See Actavis*, 570 U.S. at 144 (the "vast majority of potential profits for a generic drug manufacturer materialize during" the first six months of marketing).

Term Effects and Long-Term Impact (Aug. 2011), *available at* https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf, at p. 16 ("For each company, the graph includes all AGs marketed pursuant to the company's NDAs, whether marketed internally (e.g., by a subsidiary), or through an external generic partner.").[13]

113. It is economically rational for a brand manufacturer that intends to launch an AG to do so contemporaneously with the first ANDA filer's launch. The Supreme Court observed that "the vast majority of potential profits for a generic drug manufacturer materialize during the 180-day exclusivity period." *Actavis*, 150 U.S. at 144.

114. Novartis would have launched an AG of Exforge upon market entry by Par in the absence of the anticompetitive Agreement here.

115. Even with the most conservative estimates, the payment flowing from Novartis to Par via the Agreement had a cash value in the hundreds of millions of dollars. The payment induced Par to stay out of the Exforge market in return for sharing monopoly profits—a naked market allocation and thus a *per se* violation of the Sherman Act. Even under the Rule of Reason, however, the payment is unexplained and Defendants will have no pro-competitive justification or other legitimate explanation for the payment.

116. But for the Agreement, Par would have launched generic Exforge as early as September 21, 2012, but no later than March 29, 2013. Par would have launched, without a license from Novartis, on September 21, 2012, when the '578 patent expired, because '197 and '728

[13] *See also* FDA's Listing of Authorized Generics as of March 28, 2018, available at: http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/UCM183605.

patents were not a bar to Par's entry. This is evident by the fact that Alembic Pharmaceuticals ("Alembic"), Aurobindo Pharma ("Aurobindo"), Invagen Pharmaceuticals ("Invagen"), Mylan, N.V., ("Mylan"), Teva Pharmaceutical Industries, Ltd. ("Teva"), Torrent Pharms, Ltd. ("Torrent"), Novel Labs, Inc. ("Novel"), and Lupin Pharmaceuticals, Inc. ("Lupin") – all of whom had filed ANDAs to sell generic Exforge – all launched their generic products on or about March 30, 2015, when Par's 180-day exclusivity expired.

117. On information and belief, Mylan, Teva, Torrent, Novel, and Lupin launched without a license from Novartis, despite the fact that the '197 and '728 Patents had not yet expired as of the time those companies launched their generic versions of Exforge.

118. Had Par launched its generic version of Exforge as early as September 21, 2012, but no later than March 28, 2013, at least one subsequent filer would have obtained final FDA approval and launched an additional generic equivalent of Exforge immediately upon expiration of Par's 180-day exclusivity period.

119. On information and belief, the primary reason why Par did not launch on September 21, 2012 when the '578 Patent expired was not related to any infringement risk flowing from the '197 and '728 Patents. Rather, it was because both Par and Novartis leveraged the fact that Par, as the first ANDA filer, had 180 days of regulatory exclusivity during which no subsequent filer could launch an ANDA version of Exforge.

120. Both Par and Novartis recognized that delaying Par's launch in exchange for a no-AG agreement would benefit both companies. Novartis would benefit by continuing to charge ever-increasing monopoly prices for Exforge despite the fact that the '197 and '728 Patents were not barriers to generic entry. Par would benefit by (1) entering a market that Novartis grew during

the period of delay by raising prices; and (2) securing a no-AG agreement to be free from competition for the first six months after its delayed launch.

121. Alternatively, Par and Novartis would have entered into a license without a no-AG provision that provided for no delay or only nominal delay.

122. But for Defendants' ongoing performance under the Agreement, generic competition for Exforge would have occurred earlier and prices for both branded and generic versions of Exforge would have dropped. But for Defendants' ongoing, illegal, anticompetitive conduct, generic versions of Exforge would have become available as early as September 21, 2012, but no later than March 29, 2013. Plaintiff and other members of the Class would have paid lower prices for Exforge and its generic equivalents.

123. Defendants, by their conduct, have injured Plaintiff and other members of the Class by causing them to pay millions of dollars in overcharges on their purchases of Exforge and its generic equivalents.

VI. Claim Accrual and/or Tolling

124. Under the continuing tort precedent, this lawsuit is timely as a matter of law as to all overcharge sales since June 2014.

125. Under the discovery rule, this lawsuit is timely as to all overcharge sales because Plaintiff's cause of action did not accrue as to those sales until after June 2014 (*i.e.*, within the statutory period).

126. Even if Plaintiff's cause of action as to pre-June 2014 sales accrued prior to June 2014 notwithstanding the discovery rule, the running of the statutory period was suspended under tolling doctrines.

127. Many of the overcharges alleged herein occurred during the limitations period. To the extent some overcharges occurred prior to the four-year period of the filing of this Complaint, Plaintiff and members of the Class had no knowledge, or reason to know despite the exercise of reasonable diligence, of Defendants' unlawful scheme of Novartis's pledge to not launch an AG, from the date of the consummation of the Agreement to Novartis's failure to launch an AG of Exforge.

128. Defendants also engaged in efforts to conceal from Plaintiff and the Class the existence of their cause of action.

129. Defendants efforts included concealing from Plaintiff any of the unlawful terms of the Agreement that could have put Plaintiff on notice that the Agreement would operate to preclude Novartis from launching an AG for the first six months following Par's launch.

130. Even when limited information about the Agreement was made available in SEC filings, the key illegal aspect of the Agreement was excluded. Specifically, while Novartis's 2011 20-F, filed on January 25, 2012, states "In the US, under a license agreement with a generics manufacturer, the product [Exforge] is expected to face generic competition beginning in October 2014," it does not state that the license agreement would operate to preclude Novartis from launching an AG for the first six months following Par's launch.

131. It was not until September 30, 2014, at the earliest—when Par's launch of its generic version of Exforge was not met with a contemporaneous launch of an AG by Novartis (either directly or through a licensee)—that Plaintiff could have suspected that the Agreement precluded an AG for some period following Par's launch. Thus, no amount of diligence could have put Plaintiff on notice of its claim until September 30, 2014, at the earliest.

132. As a result of Defendants' fraudulent concealment, all applicable statutes of limitations affecting Plaintiff's and the Class's claims have been tolled.

133. Alternatively, if the statute of limitations is not tolled, this Complaint alleges a continuing course of conduct (including conduct within the limitations period), and Plaintiff and the members of the Class can recover for damages that they suffered during the limitations period.

VII. Class Allegations

134. Plaintiff FWK brings this action as a class action under Federal Rules of Civil Procedure 23(a) and (b)(3) on behalf of itself and as representative of a class defined as follows:

> All persons or entities in the United States and its territories who purchased brand or generic Exforge directly from Novartis or Par at any time during the period from as early as September 21, 2012, until the effects of Defendants' conduct ceases (the "Class Period"). Excluded from the Class are the Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all governmental entities.

135. Joinder of the members of the Class is impracticable. Plaintiff believes the Class members are numerous and widely dispersed throughout the U.S. Further, the Class is readily identifiable from information and records in the possession of Defendants. Direct notice to the members of the Class can be made upon obtaining the relevant information and records in the possession of Defendants.

136. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff and all members of the Class were damaged by Defendants' same wrongful conduct. Specifically, they paid artificially inflated prices for Exforge tablets and were deprived of the benefits of competition from, and the choice of, cheaper generic versions of Exforge as a result of Defendants' wrongful conduct.

137. Plaintiff will fairly and adequately protect and represent the interests of the Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the Class.

138. Plaintiff and the Class are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation, and have particular experience with class action antitrust litigation involving pharmaceutical products.

139. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class, thereby making overcharge damages with respect to the Class as a whole appropriate. Such generally applicable conduct is inherent in the Defendants' wrongful conduct.

140. Questions of law and fact common to the Class include:

a. whether Defendants conspired to restrain generic competition to Exforge;

b. whether Par unlawfully agreed to delay its entry into the market for generic Exforge tablets;

c. whether Novartis paid or otherwise compensated Par in exchange for a delay in generic competition for Exforge;

d. whether Novartis's compensation to Par was necessary to yield some procompetitive benefit that is legally cognizable and nonpretextual;

e. whether Defendants' challenged conduct suppressed generic competition to Exforge;

f. whether Defendants' challenged conduct harmed competition in the market for Exforge and its AB-rated generic bioequivalents;

g. whether Novartis possessed market power in the market for Exforge and its AB-rated generic bioequivalents;

h. whether the relevant antitrust market (if a relevant market must be defined) is the market for Exforge and its AB-rated generic bioequivalents;

i. whether Defendants' activities alleged herein have substantially affected interstate commerce;

j. whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of Plaintiff and members of the Class in the nature of overcharges; and

k. the quantum of overcharges paid by Plaintiff and the Class in the aggregate.

141. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated, geographically dispersed persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

142. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

VIII. Market Power and Relevant Market

143. At all relevant times, Novartis had market power over Exforge and its AB-rated generic equivalents because Novartis had the power to maintain the price of Exforge at supra-

competitive levels without losing sales as to make the supra-competitive price unprofitable. This market power may be shown directly, and therefore no relevant market needs to be defined.

144. Direct proof exists that Novartis has monopoly power over the price of fixed combination products comprising amlodipine and valsartan. Such direct evidence includes, among other things, the abnormally-high price-cost margins enjoyed by Novartis prior to entry of generic Exforge and Novartis's ability to profitably maintain the price of Exforge well above competitive levels.

145. A small but significant, non-transitory price increase for Exforge by Novartis would not have caused a significant loss of sales to make such a price increase unprofitable.

146. Exforge is not reasonably interchangeable with any products other than AB-rated generic versions of Exforge.

147. Novartis needed to control only Exforge and its AB-rated generic equivalents, and no other products, in order to maintain the price of Exforge profitably at supra-competitive prices. Only the market entry of a competing, AB-rated generic version of Exforge would render Novartis unable to profitably maintain its current prices of Exforge without losing substantial sales.

148. At all relevant times, Novartis has sold Exforge at prices well in excess of the competitive price.

149. At all relevant times, Novartis had, and exercised, the power to exclude and restrict competition to Exforge and AB-rated bioequivalents.

150. At all relevant times, Novartis enjoyed high barriers to entry with respect to competition in the relevant product market due to patent and other regulatory protections and high costs of entry and expansion.

151. To the extent Plaintiff is legally required to prove market power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant product market is Exforge (in all its forms and dosage strengths) and bioequivalent generic versions of Exforge. During the relevant time, Novartis has been able to profitably maintain the price of Exforge tablets well above competitive levels.

152. The relevant geographic market is the U.S. and its territories.

153. Novartis's anticompetitive payment to Par demonstrates that Novartis enjoyed market power with respect to Exforge (in all its forms and dosage strengths) and bioequivalent generic versions of Exforge.

154. At competitive price levels, Exforge does not exhibit significant positive cross-price elasticity of demand with any product other than AB-rated generic versions of Exforge.

155. Novartis's market share in the relevant market was either 100% or close to 100% at all relevant times.

156. During the relevant period, Defendants' anticompetitive conduct has significantly damaged direct purchasers consumers through a reduction of output and higher prices, caused by an elimination or reduction of lower cost generic Exforge throughout the U.S. and its territories.

157. Other drugs that are not AB-rated to Exforge cannot be substituted automatically for Exforge by pharmacists, do not exhibit substantial cross-price elasticity of demand with respect to Exforge, and thus are not economic substitutes for, nor reasonably interchangeable with, Exforge.

158. The existence of other products designed to treat hypertension or other illnesses treated by Exforge has not significantly constrained Novartis's pricing of Exforge.

159. On information and belief, Novartis has never lowered the price of Exforge in response to the pricing of other branded or generic treatments.

IX. Market Effects and Damages to the Class

160. The Agreement enabled Defendants to: (a) prevent and delay the entry of less expensive generic versions of Exforge products in the U.S. and its territories; (b) fix, raise, maintain, or stabilize the price of Exforge products; and (c) allocate 100% of the U.S. market for Exforge and its generic equivalents to Novartis.

161. The '578 Patent expired on March 21, 2012, and the attached pediatric exclusivity expired on September 21, 2012. Par launched its generic on September 30, 2014, and at least eight later filing generics (Alembic, Aurobindo, Invagen, Mylan, Teva, Torrent, Novel, and Lupin) launched their versions on or shortly after March 30, 2015. Novartis launched an authorized generic of Exforge on or shortly after March 30, 2015 through its subsidiary, Sandoz.

162. But for the anticompetitive conduct alleged above, Par would have entered the market with its generic AB-rated generic version of Exforge as early as September 21, 2012, but no later than March 29, 2013. Such sales would have occurred via market entry by Par upon Par's final FDA approval after expiry of the '578 Patent on September 21, 2012, or shortly thereafter under a license with Novartis that did not include a no-AG provision. In addition, upon market entry by Par, Novartis would have begun selling its own less expensive AG version of Exforge in direct competition with the Par generic. Other ANDA-based generic versions of Exforge, including but not limited to the Alembic, Aurobindo, Invagen, Mylan, Teva, Torrent, Novel, and Lupin products, would have followed into the market as early as 180 days after Par's launch.

163. An increasingly competitive market for Exforge and its generic equivalents would have thereafter emerged as additional generic manufacturers entered the market.

164. Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Exforge from generic competition.

165. Defendants' unlawful concerted action has delayed or prevented the sale of generic Exforge in the U.S. and unlawfully enabled Novartis to sell Exforge, and Par to sell its generic equivalent of Exforge, at artificially inflated, supra-competitive prices.

166. Typically, generic drugs are initially priced significantly below the corresponding brand drug to which they are AB-rated. As a result, upon generic entry, nearly all brand drug purchases are rapidly substituted for generic equivalents of the drug. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further due to competition among the generic manufacturers, and, correspondingly, the brand drug loses even more of its market share to the generic versions of the drug.

167. This price competition enables all purchasers of the drug to: (a) purchase generic versions of a drug at substantially lower prices; (b) purchase generic equivalents of the drug at a lower price, sooner; and/or (c) purchase the brand drug at a reduced price. Consequently, brand manufacturers have a keen financial interest in delaying and impairing generic competition, and purchasers experience substantial cost inflation from that delay and impairment.

168. But for Defendants' anticompetitive conduct, Plaintiff and members of the Class would have paid less for Exforge tablets by: (a) substituting purchases of less-expensive AB-rated generic Exforge for their purchases of more-expensive brand Exforge; (b) receiving discounts on their remaining brand Exforge purchases; and (c) purchasing generic Exforge at lower prices sooner.

169. Moreover, due to Defendants' anticompetitive conduct, other generic manufacturers were discouraged from and/or delayed in (a) launching generic versions of Exforge, and/or (b) challenging the validity or infringement of the Exforge patents in court.

170. Thus, Defendants' unlawful conduct deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

X. Antitrust Impact

171. During the relevant period, Plaintiff and members of the Class purchased substantial amounts of Exforge directly from Novartis and/or generic Exforge directly from Par. As a result of Defendants' illegal conduct, Plaintiff and members of the Class were compelled to pay, and did pay, artificially inflated prices for their Exforge tablet requirements. Those prices were substantially greater than the prices that Plaintiff and members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of Exforge and generic Exforge was artificially inflated by Defendants' illegal conduct, and (2) Plaintiff and Class members were of the opportunity to purchase lower-priced generic versions of Exforge.

172. When generic versions of Exforge were finally available, prices of generic Exforge were higher than they would have been absent Defendants' illegal conduct, and so Plaintiff and the Class have incurred overcharges on their purchases of generic Exforge as well.

173. As a consequence, Plaintiff and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

XI. Effect on Interstate Commerce

174. At all material times, Exforge, manufactured and sold by Novartis, and generic Exforge, manufactured and sold by Par, was shipped across state lines and sold to customers located outside its state of manufacture.

175. During the relevant time period, in connection with the purchase and sale of Novartis's branded Exforge and Par's generic Exforge, monies as well as contracts, bills, and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

176. During the relevant time period, various devices were used to effectuate the illegal acts alleged herein, including the U.S. mail, interstate and foreign travel, and interstate and foreign telephone commerce. Defendants' activities were within the flow of, and have substantially affected, interstate commerce.

XII. Claims for Relief

COUNT I: VIOLATION OF 15 U.S.C. § 1 AGREEMENT RESTRAINING TRADE

177. Plaintiff incorporates each preceding paragraph as though fully set forth herein.

178. Defendants have engaged in an unlawful contract that has unreasonably restrained trade or commerce in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

179. The unlawful contract consisted of Novartis and Par, their agents and affiliates and co-conspirators, both known and unknown, entering into and engaged in a continuing unlawful trust and agreement in restraint of trade and commerce in Exforge and its generic equivalents, in violation of the Sherman Act by entering into agreements to extend patent monopolies and to divide markets and allocate customers.

180. In or around 2011, Novartis and Par commenced a continuing illegal contract in restraint of trade, the purpose and effect of which was to: (a) allocate all sales of fixed combination

products comprising amlodipine and valsartan in the U.S. to Novartis; (b) prevent the sale of a generic version of Exforge in the U.S. until as late as September 30, 2014, and thereafter restrict the supply of generic versions of Exforge, thereby protecting Exforge from further generic competition; and (c) fix the price at which Plaintiff and the other members of the Class would pay for Exforge and its generic equivalents at a higher, supra-competitive price.

181. By engaging in this unlawful and continuing contract, Novartis and Par have unlawfully contracted in restraint of trade and committed a *per se* violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. In the alternative, Defendants' conduct is an unreasonable restraint of trade in violation of Section 1 when viewed under a "rule of reason" mode of analysis. Plaintiff and other members of the Class have been injured in their business and property by reason of Defendants' unlawful contract.

182. Throughout the Class Period, Plaintiff and the other members of the Class have paid more on their purchases of Exforge and its generic equivalents than they would have paid absent Defendants' illegal conduct, and/or were prevented from substituting a cheaper generic alternative for their purchases of the more expensive branded and generic Exforge.

183. But for the continuing illegal agreements between Novartis and Par (which included financial inducements to delay the launch of a less expensive generic version of Exforge), Par would have begun selling a less expensive AB-rated generic version of Exforge as early as September 21, 2012, but no later than March 29, 2013. Such sales would have occurred via market entry by Par upon Par's final FDA approval after expiry of the '578 Patent on September 21, 2012, or shortly thereafter under a license with Novartis that did not include a no-AG provision. In addition, upon market entry by Par, Novartis would have begun selling its own less expensive AG of Exforge in direct competition with the Par generic.

184. If manufacturers of generic Exforge entered the market and competed with Exforge in a full and timely fashion, Plaintiff and other members of the Class would have substituted lower-priced generic versions of Exforge for the higher-priced brand name Exforge for some or all of their requirements for fixed combination products comprised of valsartan and amlodipine, and/or would have paid lower prices on some or all of such purchases.

185. During the relevant period, Plaintiff and other Class members purchased substantial amounts of Exforge tablets directly from Novartis and/or their generic equivalents directly from Par. As a result of the Defendants' illegal conduct alleged herein, Plaintiff and the other Class members were compelled to pay, and did pay, artificially inflated prices for their requirements for fixed combination products comprised of amlodipine and valsartan.

186. Plaintiff and the other Class members paid prices for such products that were substantially greater than the prices they would have paid absent the illegal conduct alleged herein because: (1) Class members were deprived of the opportunity to purchase lower-priced generic versions of Exforge instead of expensive brand name Exforge tablets; (2) Class members were forced to pay artificially inflated prices for Exforge and generic versions of Exforge; and/or (3) the price of brand name Exforge was artificially inflated by Defendants' illegal conduct.

187. There is, and was, no legitimate, non-pretextual procompetitive justification for Defendants' actions comprising the anticompetitive scheme that outweighs their harmful effect. Even if there were some conceivable justification, the scheme is and was broader than necessary to achieve such a purpose.

188. The Agreement harmed Plaintiff and the Class as set forth above.

189. The Agreement covered a sufficiently substantial percentage of the relevant market to harm competition.

190. The Agreement between Novartis and Par and their conduct under and pursuant to that Agreement constitute an illegal restraint of trade or commerce and a continuing violation of the Sherman Act.

191. As a direct and proximate result of Novartis's and Par's anticompetitive conduct, as alleged herein, Plaintiff and the Class have been harmed and have sustained substantial losses and damage to their business and property in the form of overcharges as set forth above.

COUNT II: VIOLATION OF 15 U.S.C. § 2
MONOPOLIZATION

192. Plaintiff hereby incorporates each preceding paragraph as though fully set forth herein.

193. This claim is pled as to Novartis.

194. At all relevant times, Novartis possessed substantial market power (*i.e.*, monopoly power) in the relevant market. Novartis possessed the power to control prices in, prevent prices from falling in, and exclude competitors from the relevant market.

195. Through the anticompetitive conduct, as alleged extensively above, Novartis willfully maintained monopoly power in the relevant market using restrictive or exclusionary conduct, rather than by means of greater business acumen, and injured Plaintiff and the Class thereby.

196. Novartis used various willful and exclusionary means as part of a scheme described herein to improperly maintain and extend its monopoly power in the market for Exforge and its generic equivalents, as detailed above.

197. It was Novartis's conscious object to further its dominance in the relevant market by and through the anticompetitive conduct alleged herein.

198. The goal, purpose, and/or effect of the scheme was to prevent, delay and/or minimize the success of the entry of generic competitors which would have sold generic versions of Exforge in the U.S. at prices significantly below Novartis's prices for branded Exforge, which would have effectively caused the average market price of fixed combination products comprising amlodipine and valsartan to decline dramatically.

199. The goal, purpose, and/or effect of Novartis's scheme was also to maintain and extend Novartis's monopoly power with respect to Exforge and its generic equivalents.

200. But for Novartis's ongoing, illegal, anticompetitive conduct, generic versions of Exforge would have become available as early as September 21, 2012, but no later than March 29, 2013. Plaintiff and other members of the Class would have paid lower prices for Exforge. Novartis, by its conduct, has injured Plaintiff and other members of the Class by causing them to pay hundreds of millions of dollars in overcharges on their purchases of Exforge.

201. If manufacturers of generic versions of Exforge had entered the market and competed with Exforge in a full and timely fashion, Plaintiff and other members of the Class would have substituted lower-priced generic versions of Exforge for the higher-priced brand-name Exforge for some or all of their requirements and/or would have paid lower prices for some or all of their remaining Exforge purchases.

202. During the relevant period, Plaintiff and the other Class members purchased substantial amounts of Exforge directly from Novartis and have purchased substantial amount of the generic version of Exforge from Par. As a result of Novartis's illegal conduct alleged herein, Plaintiff and the other members of the Class have been compelled to pay, and have paid, artificially inflated prices for their requirements for fixed combination products comprising amlodipine and valsartan. Plaintiff and the other members of the Class paid prices for such products that were

substantially greater than the prices that they would have paid absent the illegal conduct alleged herein, because: (1) Class members were deprived of the opportunity to purchase lower priced generic versions of Exforge instead of expensive brand-name Exforge, which Plaintiff and the Class would have purchased in place of branded Exforge had they had the opportunity; (2) Class members were or will be forced to pay artificially inflated prices for generic versions of Exforge; and/or (3) the price of branded Exforge was artificially inflated by Novartis's illegal conduct. Novartis's scheme was in the aggregate an act of monopolization undertaken with the specific intent to monopolize the market for amlodipine and valsartan in the U.S., in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

203. Novartis's anticompetitive conduct harmed competition as alleged herein.

204. There is and was no legitimate, nonpretextual procompetitive justification for Novartis's actions comprising the anticompetitive conduct that outweighs the scheme's harmful effects. Even if there were some conceivable such justification, the conduct is and was broader than necessary to achieve such a purpose.

205. As a direct and proximate result of Novartis's illegal and monopolistic conduct, as alleged herein, Plaintiff and the Class were harmed.

COUNT III: VIOLATION OF 15 U.S.C. § 2
ATTEMPTED MONOPOLIZATION

206. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

207. This claim is pled as to Novartis.

208. Through the Agreement and related conduct, Novartis specifically intended to maintain monopoly power in the relevant market. It was Novartis's conscious objective to control prices and/or to exclude competition in the relevant market.

209. The natural and probable consequence of Novartis's anticompetitive conduct, which was intended by it, and plainly foreseeable to it, was to control prices and exclude competition in the relevant market.

210. There was a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Novartis would succeed in and achieve its goal of maintaining monopoly power in the relevant market.

211. As a direct and proximate result of Novartis's illegal and monopolistic conduct, Plaintiff and the Class were harmed as alleged herein.

COUNT IV: VIOLATION OF 15 U.S.C. § 2
CONSPIRACY TO MONOPOLIZE

212. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

213. Defendants Novartis and Par combined, conspired, and contracted between and among themselves to unreasonably and unlawfully restrain and monopolize trade and to attempt to monopolize trade with specific intent, and Novartis did, in fact, monopolize trade in the U.S. in the market for Exforge and its generic equivalents, thereby eliminating competition in that market.

214. Novartis and Par, their agents and affiliates and co-conspirators, both known and unknown, entered into and engaged in a continuing unlawful trust and Agreement in restraint of trade and commerce in Exforge and its generic equivalents, in violation of the Sherman Act, by entering into agreements to extend patent monopolies and to divide markets and allocate customers.

215. Novartis and Par each committed at least one overt act in furtherance of the conspiracy.

216. The purpose and effect of such agreements was to fix, raise, stabilize, and maintain the prices for Exforge and its generic equivalents at supracompetitive levels, which increased prices paid by Plaintiff and the Class.

217. During the Class Period, Plaintiff and the other members of the Class purchased substantial amounts of Exforge directly from Novartis, and purchased substantial amounts of generic versions of Exforge directly from Par. As a result of Defendants' illegal conduct, alleged herein, Plaintiff and other members of the Class have been compelled to pay, and have paid, artificially inflated prices for their requirements for fixed combination products comprising amlodipine and valsartan. Plaintiff and other members of the Class paid prices for such products that were substantially greater than the prices they would have paid absent the illegal conduct alleged herein because: (1) Class members were deprived of the opportunity to purchase lower-priced generic versions of Exforge instead of expensive brand-name Exforge and would have purchased such lower-priced generic in place of branded Exforge had they had the opportunity; (2) Class members were or will be forced to pay artificially inflated prices for generic versions of Exforge; and/or (3) the price of brand-name Exforge was artificially inflated by Defendants' illegal conduct.

XIII. Demand for Judgment

WHEREFORE, FWK, on behalf of itself and the Class, respectfully requests that the Court:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class, and declare FWK to be a representative of the Class;

B. Enter joint and several judgments against the Defendants and in favor of FWK and the Class;

C. Award the Class damages (*i.e.*, three times overcharges) in an amount to be determined at trial; and

D. Award FWK and the Class their costs of suit, including reasonable attorneys' fees as provided by law.

XIV. Jury Demand

218. Pursuant to Federal Rule of Civil Procedure 38, FWK, on behalf of itself and the proposed Class, demands a trial by jury on all issues so triable.

Dated: June 29, 2018

Respectfully submitted,

KAPLAN FOX & KILSHEIMER, LLP

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